

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
DALLAS COUNTY HOSPITAL DISTRICT
D/B/A PARKLAND HEALTH AND HOSPITAL SYSTEM**

I. PREAMBLE

Dallas County Hospital District d/b/a Parkland Health and Hospital System (Parkland) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). On September 28, 2011, Parkland entered into a Systems Improvement Agreement (SIA) with the Centers for Medicare and Medicaid Services. In accordance with the terms of the SIA, in November 2011 Parkland retained an Independent Consultative Expert (ICE). As amended by the parties to the SIA, the SIA requires completion of a Medicare certification survey (Survey) on or before August 31, 2013. Contemporaneously with this CIA, Parkland is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Parkland under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Parkland’s final annual report; or (2) any additional materials submitted by Parkland pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Covered Persons” includes:
 - a. all owners, officers, managers, and employees of Parkland;
 - b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Parkland, excluding vendors whose sole connection with Parkland is selling or otherwise providing medical supplies or equipment to Parkland and who do not bill the Federal health care programs for such medical supplies or equipment; and
 - c. all physicians and other non-physician practitioners who are members of Parkland’s active medical staff.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Billing and Reimbursement Covered Persons” includes all Covered Persons involved, directly or in a supervisory role, in the preparation or submission of claims for reimbursement from, or cost reports to, any Federal health care program.

3. “Clinical Quality Covered Persons” includes all Covered Persons involved in the delivery of patient care items or services at Parkland or involved in quality assurance or the monitoring of clinical quality at Parkland.

III. CORPORATE INTEGRITY OBLIGATIONS

Parkland shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Management and Oversight

1. *Compliance Officer.* Parkland has appointed a Chief Compliance Officer (Compliance Officer). Parkland shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care

program requirements. The Compliance Officer must have sufficient compliance experience to effectively oversee the implementation of the requirements of this CIA. The Compliance Officer is, and shall continue to be, a member of senior management of Parkland; does, and shall continue to, report directly to the Chief Executive Officer of Parkland; does, and shall continue to, make periodic (at least quarterly) reports regarding compliance matters directly to the Audit and Compliance Committee of the Board of Managers of Parkland, or its successor; and is, and shall continue to be, authorized to report on such matters to the Board of Managers (Board) at any time. The Compliance Officer is not, and shall not be, subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer is, and shall continue to be, responsible for monitoring the day-to-day compliance activities engaged in by Parkland as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Parkland shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Parkland has appointed an Executive Compliance Committee (Compliance Committee) and shall continue to maintain a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Parkland's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

Parkland shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Chief Quality and Safety Officer.* Within 90 days after the completion of the Survey, Parkland will appoint a Covered Person to serve as its Chief Quality and Safety Officer. Parkland shall maintain, during the term of the CIA, a Covered Person to serve as its Chief Quality and Safety Officer. The Chief Quality and

Safety Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with professionally recognized standards of care. The Chief Quality and Safety Officer shall be a member of senior management of Parkland, shall report directly to the Chief Medical Officer of Parkland, shall make periodic (at least quarterly) reports regarding quality assurance matters directly to the Quality and Safety Committee of the Board, and shall be authorized to report on such matters to the Board at any time. The Chief Quality and Safety Officer shall not be subordinate to the General Counsel or Chief Financial Officer. The Chief Quality and Safety Officer shall be responsible for monitoring the day to day quality of care and patient safety activities engaged in by Parkland. Any non-quality assurance job responsibilities of the Chief Quality and Safety Officer shall be limited and must not interfere with the Chief Quality and Safety Officer's ability to perform the activity outlined in this CIA. The Chief Quality and Safety Officer shall have sufficient quality assurance experience to perform the responsibilities described in this paragraph.

Parkland shall report to OIG, in writing, any change in the identity of the Chief Quality and Safety Officer, or any actions or changes that would affect the Chief Quality and Safety Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

4. *Quality, Safety, and Performance Improvement Department.*

Parkland has appointed and shall continue to maintain a Quality, Safety, and Performance Improvement Department comprised of the Chief Quality and Safety Officer, senior officers (including the Chief Medical Officer and the VP of Quality and Performance Improvement), and other clinical quality staff (including the Patient Safety Officer). The Chief Quality and Safety Officer will chair the Quality, Safety, and Performance Improvement Department. The Quality, Safety, and Performance Improvement Department is responsible for monitoring: 1) clinical quality at Parkland, 2) the Quality, Safety, and Performance Improvement Program, 3) physician credentialing, privileging, and peer review programs, 4) evidence-based medicine programs, 5) standards of clinical excellence, 6) utilization management and review, and 7) other quality performance standards.

a. *Quality, Safety, and Performance Improvement Program.*

The Quality, Safety, and Performance Improvement Department shall ensure that, within 90 days after the completion of the Survey, Parkland establishes and implements a program for performing internal quality audits and reviews (hereinafter "Quality, Safety, and Performance

Improvement Program”). The Quality, Safety, and Performance Improvement Program shall make findings as to:

- i. whether the patients at Parkland are receiving the quality of care consistent with professionally recognized standards of care and any other applicable Federal and State statutes, regulations, and directives;
 - ii. whether Parkland is effectively reviewing quality of care related incidents and completing root cause analyses; and
 - iii. whether Parkland’s action plans in response to identified quality of care problems are appropriate, timely, implemented, and enforced.
- b. *Quality of Care Dashboard.* The Quality, Safety, and Performance Improvement Department, in consultation with the QRO required under section III.D.1.b of this CIA, shall create and implement a “Quality of Care Dashboard” (Dashboard), which will function as a performance scorecard for Parkland. Within 90 days after the completion of the Survey, the Quality, Safety, and Performance Improvement Department shall: (1) identify and establish the overall quality improvement goals for Parkland based on its assessment of Parkland’s quality of care risk areas; (2) identify and establish quality indicators related to those goals that Parkland will monitor through the Dashboard; and (3) establish performance metrics for each quality indicator. The Quality, Safety, and Performance Improvement Department shall measure, analyze, and track the performance metrics for the quality indicators on a monthly basis, monitoring progress towards the quality improvement goals. At least semi-annually, the Quality, Safety, and Performance Improvement Department shall review the quality indicators to determine if revisions are appropriate and shall make any necessary revisions based on such review.
- c. Parkland shall report to OIG, in writing, any changes in the composition of the Quality, Safety, and Performance

Improvement Department, or any actions or changes that would affect the Quality, Safety, and Performance Improvement Department's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

5. *Board of Managers Compliance Obligations.* The Board shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, the obligations of this CIA, and professionally recognized standards of care. Prior to the Effective Date, the Board retained a corporate governance and compliance expert (Outside Expert). The Outside Expert shall continue to assist the Board meet its duties to review and assess the performance of the Compliance Program and the Quality of Care and Patient Safety Program. In addition, the Board shall, at a minimum, be responsible for the following:

- a. Receiving and assessing reports and other information from:
 - i. management;
 - ii. the Audit and Compliance and Quality of Care and Patient Safety Committees of the Board; and
 - iii. external advisors or counsel as the Board deems appropriate;
- b. meeting at least quarterly to review and assess Parkland's Compliance and Quality, Safety, and Performance Improvement Programs;
- c. For each Reporting Period of the CIA, adopt a resolution, signed by each member of the Board, summarizing its review and oversight of Parkland's compliance with Federal health care program requirements, the obligations of this CIA, and professionally recognized standards of care. At minimum, the resolution shall include the following language:

“The Board of Managers has made a reasonable inquiry into the operations of Parkland's Compliance and Quality, Safety and Performance Improvement Programs, including the performance of the Compliance Officer, the Compliance Committee, the Chief Quality & Safety Officer, and the

Quality, Safety & Performance Improvement Department. Based on its inquiry and review, the Board of Managers has concluded that, to the best of its knowledge, Parkland has implemented effective Compliance and Quality, Safety and Performance Improvement Programs and Parkland is in compliance with Federal health care programs requirements, professionally recognized standards of care, and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program and/or an effective Quality, Safety and Performance Improvement Program.

- d. Parkland shall report to OIG, in writing, any changes in the composition of the Board, the Audit and Compliance and Quality of Care and Patient Safety Committees of the Board, and/or any actions or changes that would affect the Board’s ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

6. *Audit and Compliance Committee of the Board of Managers.* The Board has appointed a standing Audit and Compliance Committee. The Audit and Compliance Committee is responsible for the review and oversight of matters related to compliance with the requirements of Federal health care programs and the obligations of this CIA. The Audit and Compliance Committee, and any successor Committee formed by the Board shall ensure that Parkland is appropriately identifying, assessing, and correcting compliance concerns and risks. The Audit and Compliance Committee shall, at a minimum:

- a. Meet at least quarterly;
- b. Review and oversee Parkland’s Compliance Program, including but not limited to the performance of the Compliance Officer and the Compliance Committee;
- c. Arrange for the performance of a review of the effectiveness of Parkland’s Compliance Program (Compliance Program Review) for each Reporting Period of the CIA, as well as a

report of each such review (Compliance Program Review Report);

- d. Consider the results of the Compliance Program Review as part of the review and assessment of Parkland's Compliance Program;
- e. Report its assessment of Parkland's Compliance Program Review to the Board and provide the Board with a copy of the Compliance Program Review Report; and
- f. Provide a copy of the Compliance Program Review Report to OIG in each Annual Report submitted by Parkland.

7. *Quality of Care and Patient Safety Committee of the Board of Managers.* The Board has appointed a standing Quality of Care and Patient Safety Committee. The Quality of Care and Patient Safety Committee is responsible for the review and oversight of matters related to professionally recognized standards of care and the obligations of this CIA. The Quality of Care and Patient Safety Committee shall ensure that Parkland is appropriately identifying and correcting quality of care problems. The Quality of Care and Patient Safety Committee shall, at a minimum:

- a. Meet at least quarterly;
- b. Review and oversee Parkland's Quality, Safety, and Performance Improvement Program, including but not limited to the performance of the Chief Quality and Safety Officer and the Quality, Safety, and Performance Improvement Department;
- c. Review and respond to the Dashboard to ensure that Parkland implements effective responses when potential quality problems are indicated on the Dashboard or when quality indicators show that Parkland is not meeting its established goals;
- d. Within 90 days of the completion of the Survey, the Quality of Care and Patient Safety Committee shall arrange for the performance of a review of the effectiveness of Parkland's Quality, Safety, and Performance Improvement Program (Quality Program Review) to cover each Reporting Period of

the CIA, as well as a report of each such review (Quality Program Review Report);

- e. Consider the results of the Quality Program Review as part of the review and assessment of Parkland's Quality Programs;
- f. Report its assessment of Parkland's Quality Program Review to the Board and provide the Board with a copy of the Quality Program Review Report; and
- g. Provide a copy of the Quality Program Review Report to OIG in each Annual Report submitted by Parkland.

B. Written Standards

1. *Code of Conduct.* Parkland adopted a Code of Conduct and Ethics (Code of Conduct). To the extent not already accomplished, within 90 days after the Effective Date, Parkland shall revise, implement, and distribute the written Code of Conduct to all Covered Persons. Parkland shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Parkland's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. Parkland's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Parkland's own Policies and Procedures;
- c. the requirement that all of Parkland's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Parkland, suspected violations of any Federal health care program requirements or of Parkland's own Policies and Procedures;
- d. the requirement that all of Parkland's Covered Persons shall immediately report to the Chief Quality and Safety Officer, or other appropriate individual designated by Parkland, credible

allegations of patient harm and such report shall be complete, full, and honest;

- e. the possible consequences to both Parkland and Covered Persons of failure to comply with Federal health care program requirements and with Parkland's own Policies and Procedures and the failure to report such noncompliance; and
- f. the right of all individuals to use the Disclosure Program described in Section III.E, and Parkland's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the promulgation of any revision to the Code of Conduct, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Parkland's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Parkland shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized and approved by the Board. Each Covered Person shall certify, in writing or electronic form, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* To the extent not already completed, Parkland shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA, Provider's compliance with Federal health care program requirements, and addressing the following subject areas:

- a. *Billing and Reimbursement.* These Policies and Procedures shall be designed to ensure that Parkland complies with the Federal health care programs requirements on billing and reimbursement, shall be implemented within 90 days after the Effective Date, and shall include the following:

- i. ensuring the proper and accurate preparation and submission of claims to Federal health care programs;
 - ii. ensuring the proper and accurate documentation of medical records;
 - iii. ensuring the proper and accurate submission of cost reports submitted to the Federal health care programs;
 - iv. conducting periodic billing and coding reviews and audits at Parkland; and
 - v. reporting and repayment of all identified Overpayments to Federal health care programs and other payors.
- b. *Clinical Quality.* These Policies and Procedures shall be designed to promote the delivery of patient care items or services at Parkland that meet professionally recognized standards of care and are reasonable and appropriate to the needs of Federal health care program beneficiaries, shall be implemented within 90 days after completion of the Survey, and shall include the following:
- i. ensuring the appropriate documentation of medical records;
 - ii. measuring, analyzing, and tracking quality indicators, including adverse patient events, and other aspects of performance that relate to processes of care, hospital services, and operations;
 - iii. incorporating quality indicator data, including patient care data and other relevant data to monitor the effectiveness and safety of services and quality of care and to identify opportunities for improvement and changes that will lead to improvement;
 - iv. setting priorities for performance improvement activities that: (1) focus on high risk, high-volume, or problem-prone areas; (2) consider the incidence,

- prevalence, and severity of problems in those areas; and (3) affect health outcomes, patient safety, and quality of care;
- v. tracking medical errors and adverse patient events, analyzing their causes, and implementing preventive actions and mechanism that include feedback and learning throughout Parkland;
 - vi. conducting quality assessment and performance improvement projects, including periodic clinical quality audits;
 - vii. collecting and reporting quality assessment and performance improvement data to relevant data registries;
 - viii. periodically reporting quality assessment and performance improvement data to the Quality of Care and Patient Safety Committee;
 - ix. collecting, verifying, and assessing current licensure, education, relevant training, experience, ability, and current competence to perform requested privileges;
 - x. monitoring practitioners with current privileges by the review of clinical practice patterns, ongoing case review, proctoring, and discussion with other individuals involved in the care of patients;
 - xi. implementing and monitoring medical staff peer review; and
 - xii. implementing effective responses when clinical quality problems are discovered.
- c. *Performance Standards and Incentives.* These Policies and Procedures shall address performance standards for Parkland corporate management, shall be implemented within 90 days after the Effective Date (unless related to quality, in which

case they shall be implemented within 90 days after the completion of the survey), and shall include the following:

- i. clinical quality measures;
- ii. compliance program effectiveness measures; and
- iii. compensation and incentive awards directly linked to clinical quality measures and compliance program effectiveness measures.

To the extent not already completed, within 90 days after the Effective Date, the Billing and Reimbursement Policies and Procedures and the Performance Standards and Incentives Policies and Procedures shall be distributed to all Covered Persons. To the extent not already completed, within 90 days after the completion of the Survey, the Clinical Quality Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Parkland shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be distributed to all Covered Persons.

C. Training and Education

1. *General Training.* Within 90 days after the Effective Date, Parkland shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Parkland's:

- a. CIA requirements; and
- b. Compliance Program, including the Code of Conduct.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Billing and Reimbursement Training.* Within 90 days after the Effective Date, each Billing and Reimbursement Covered Person shall receive at least four hours of Billing and Reimbursement Training in addition to the General Training required above. This Billing Reimbursement Training must include a discussion of the following topics:

- a. the Federal health care program requirements regarding the accurate coding and submission of claims;
- b. policies, procedures, and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for violations of the Federal health care program requirements;
- f. examples of proper and improper claims submission practices; and
- g. Policies and Procedures for the reporting and repayment of Overpayments to Federal health care programs and other payors.

New Billing and Reimbursement Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Billing and Reimbursement Covered Persons, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Billing and Reimbursement Training described in this section, each Billing and Reimbursement Covered Person shall receive at least two hours of Billing and Reimbursement Training, in addition to the General Training, in each subsequent Reporting Period.

3. *Clinical Quality Training.* Within 90 days after the completion of the Survey, each Clinical Quality Covered Person shall receive at least four hours of

Clinical Quality Training in addition to the General Training required above. This Clinical Quality Training must include a discussion of the following topics:

- a. Parkland's policies, procedures, and other requirements relating to clinical quality, including but not limited to comprehensive clinical audits, physician credentialing, privileging, and peer review programs, evidence based medicine programs, standards of clinical excellence, utilization management and review, clinical quality measures, and the other requirements under Sections III.B.2.d and III.B.2.e;
- b. the personal obligation of each individual involved in the delivery of patient care items or services at Parkland or involved in the monitoring of clinical quality at Parkland to know the applicable legal requirements and Parkland's Clinical Quality Policies and Procedures;
- c. the personal obligation of each individual to immediately report to the Chief Quality and Safety Officer, or other appropriate individual designated by Parkland, credible allegations of patient harm;
- d. the legal sanctions for violating the Federal health care program requirements; and
- e. examples of proper and improper patient care at Parkland.

New Clinical Quality Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Clinical Quality Covered Persons, or within 90 days after the completion of the Survey, whichever is later.

After receiving the initial Clinical Quality Training described in this section, each Clinical Quality Covered Person shall receive at least two hours of Clinical Quality Training, in addition to the General Training, in each subsequent Reporting Period.

4. *Board Member Training.* Within 120 days after the Effective Date, Parkland shall provide at least two hours of training to each member of the Board, in addition to the General Training. This training shall address the responsibilities of Board members and corporate governance. In November 2012, the Outside Expert provided the Board with a report on the fiduciary duties of Board members, including their oversight

responsibilities with respect to Parkland's compliance, quality, and patient safety programs (Expert Report).

New members of the Board shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later. New members of the Board shall receive a copy of the Expert Report within 30 days of appointment.

5. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials.

6. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

7. *Update of Training.* Parkland shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information.

8. *Computer-based Training.* Parkland may provide the training required under this CIA through appropriate computer-based training approaches. If Parkland chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

9. *Exception for Active Medical Staff Members.* Parkland shall make the General Training, Billing and Reimbursement Training, and Clinical Quality Training (as appropriate) described in this section available to all of Parkland's active medical staff members and shall use its best efforts to encourage such active medical staff members to complete the training. The Compliance Officer shall maintain records of all active medical staff members who receive training, including the type of training and the date received.

D. Review Procedures

1. *Engagement of Review Organizations.*

- a. Within 90 days after the Effective Date, Parkland shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Billing Independent Review Organization” or “Billing IRO”), to perform the reviews listed in Section III.D.4 and Section III.D.6. The applicable requirements relating to the Billing IRO(s) are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. Within 60 days after the Effective Date, Parkland shall retain an entity, selected by OIG after consultation with Parkland, (hereinafter “Quality Review Organization” or “QRO”), to perform the review listed in Section III.D.5. The applicable requirements relating to the QRO are outlined in Appendix B to this CIA, which is incorporated by reference.
- c. The term “Review Organization” or “RO” without qualification refers to both the Billing IRO(s) and the Quality RO.

2. *Retention of Records.* The ROs and Parkland shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the ROs and Parkland) related to the reviews.

3. *Type of Reviews.* The following reviews shall be performed by ROs to be engaged and retained by Parkland during the term of the CIA: (a) Claims Review; (b) Unallowable Costs Review; and (c) Clinical Quality Systems Review (collectively the “External Reviews”). The requirements for the External Reviews are provided below and in Appendices C and D to this CIA, which are hereby incorporated by reference into the CIA.

4. *Claims Review.* The Billing IRO shall review Parkland’s coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix C to this CIA.

5. *Clinical Quality Systems Review.* The QRO shall assess the effectiveness, reliability, and thoroughness of Parkland's quality of care and patient safety systems, as outlined in Appendix D to this CIA.

6. *Unallowable Cost Review.* For the first Reporting Period, the Billing IRO shall conduct a review of Parkland's compliance with the unallowable cost provisions of the Settlement Agreement. The Billing IRO shall determine whether Parkland has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable costs analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Parkland or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the Billing IRO shall determine if such adjustments were proper. In making this determination, the Billing IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

7. *Unallowable Cost Review Report.* The Billing IRO shall prepare a report based upon the Unallowable Cost Review performed (Unallowable Cost Review Report). The Unallowable Cost Review Report shall include the Billing IRO's findings and supporting rationale regarding the Unallowable Cost Review and whether Parkland has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

8. *Validation Review.* In the event OIG has reason to believe that: (a) Parkland's Claims Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the Billing IRO's findings or Claims Review or Unallowable Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review or Unallowable Cost Review results are inaccurate (Validation Review). Parkland shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Parkland's final Annual

Report shall be initiated no later than one year after Parkland's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Parkland of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Parkland may request a meeting with OIG to: (a) discuss the results of any Claims Review or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or Unallowable Cost Review or to correct the inaccuracy of the Claims Review or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. Parkland agrees to provide any additional information as may be requested by OIG under this Section III.D.6-7 in an expedited manner. OIG will attempt in good faith to resolve any External Review issues with Parkland prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

9. *Independence and Objectivity Certification.* The Billing IRO shall include in its report(s) to Parkland a certification that the Billing IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Disclosure Program

Parkland has established and shall continue to maintain a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Parkland's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Parkland shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she

has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Parkland shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

F. Ineligible Persons

1. *Definitions.* For purposes of this CIA:

a. an “Ineligible Person” shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. “Exclusion Lists” include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration’s System for Award Management (available through the Internet at <http://www.sam.gov>).

2. *Screening Requirements.* Parkland shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Parkland shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Parkland shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Parkland shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in Section III.F affects Parkland's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Parkland understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Parkland may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Parkland meets the requirements of Section III.F.

3. *Removal Requirement.* If Parkland has actual notice that a Covered Person has become an Ineligible Person, Parkland shall remove such Covered Person from responsibility for, or involvement with, Parkland's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Parkland has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term or during the term of a physician's or

other practitioner's medical staff privileges, Parkland shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, Parkland shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Parkland conducted or brought by a governmental entity or its agents involving an allegation that Parkland has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Parkland shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Repayment of Overpayments

1. *Definition of Overpayments.* For purposes of this CIA, an "Overpayment" shall mean the amount of money Parkland has received in excess of the amount due and payable under any Federal health care program requirements.

2. *Repayment of Overpayments*

- a. If, at any time, Parkland identifies or learns of any Overpayment, Parkland shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 30 days after identification, Parkland shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies.

- b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to Policies and Procedures established by the payor should be handled in accordance with such Policies and Procedures.

I. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or
- d. the filing of a bankruptcy petition by Parkland.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Parkland determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event under Section III.I.1, Parkland shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall be made at the same time as the repayment to the payor required in Section III.H, and shall include:

- a. a copy of the notification and repayment to the payor required in Section III.H.2;
- b. a description of the steps taken by Parkland to identify and quantify the Overpayment;

- c. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- d. a description of Parkland's actions taken to correct the Reportable Event; and
- e. any further steps Parkland plans to take to address the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.I.1.b and c.* For Reportable Events under Section III.I.1.b and III.I.1.c, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of Parkland's actions taken to correct the Reportable Event;
- c. any further steps Parkland plans to take to address the Reportable Event and prevent it from recurring; and
- d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Parkland to identify and quantify the Overpayment.

5. *Reportable Events under Section III.I.1.d.* For Reportable Events under Section III.I.1.d, the report to OIG shall include:

- a. a complete description of the Reportable Event;
- b. any further steps Parkland plans to take to address the Reportable Event; and
- c. documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the

Stark Law) should be submitted by Parkland to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.H.2 that require repayment to the payor of any identified Overpayment within 30 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location

In the event that, after the Effective Date, Parkland changes locations or closes a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Parkland shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location

In the event that, after the Effective Date, Parkland purchases or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Parkland shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Parkland currently submits claims. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location

In the event that, after the Effective Date, Parkland proposes to sell any or all of its business units or locations that are subject to this CIA, Parkland shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION, ANNUAL, AND INDEPENDENT CONSULTATIVE EXPERT REPORTS

A. Implementation Report

Within 90 days after the completion of the Survey, Parkland shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall include, at a minimum:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the name, address, phone number, and position description of the Chief Quality and Safety Officer required by Section III.A.3, and a summary of other non-quality assurance job responsibilities the Chief Quality and Safety Officer may have;
4. the names and positions of the members of the Quality, Safety, and Performance Improvement Department required by Section III.A.4;
5. the names and qualifications of the members of the Audit and Compliance Committee required by Section III.A.6.;
6. the names and qualifications of the members of the Quality of Care and Patient Safety Committee required by Section III.A.7.;
7. the name, address, phone number, and qualifications of the Outside Expert to the Board required by Section III.A.5;
8. a description of the Quality, Safety, and Performance Improvement Program required by Section III.A.4.a;
9. a description of the 1) quality improvement goals, 2) quality indicators, and 3) performance metrics identified in the design of Quality of Care Dashboard pursuant to Section III.A.4.b;
10. a copy of Parkland's Code of Conduct required by Section III.B.1;

11. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);

12. a summary of all Policies and Procedures required by Section III.B.2 (copies of the Policies and Procedures shall be made available to OIG upon request);

13. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions; and
- c. with respect to active medical staff members, the number and percentage who completed the training, the type of training and the date received, and a description of Parkland's efforts to encourage medical staff members to complete the training.

A copy of all training materials and the documentation supporting this information shall be made available to OIG upon request.

14. a description of the Disclosure Program required by Section III.E;

15. the following information regarding the Billing IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the Billing IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between Parkland and the Billing IRO; and (e) a certification from the Billing IRO regarding its professional independence and objectivity with respect to Parkland;

16. a description of the process by which Parkland fulfills the requirements of Section III.F regarding Ineligible Persons;

17. a list of all of Parkland's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the

corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Parkland currently submits claims;

18. a description of Parkland's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

19. the certifications required by Section V.C.

B. Annual Reports

Parkland shall submit to OIG annually a report with respect to the status of, and findings regarding, Parkland's compliance and quality assurance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance or non-quality assurance job responsibilities of the Compliance Officer or Chief Quality and Safety Officer;

2. any change in the membership of the Compliance Committee, Quality, Safety, and Performance Improvement Department, Audit and Compliance Committee, or Quality of Care and Patient Safety Committee described in Section III.A;

3. any change in the identity of the Outside Expert required by Section III.A.5;

4. the Board resolution required by Section III.A.5;

5. a summary of any changes or amendments to Parkland's Quality, Safety, and Performance Improvement Program required by Section III.A.4.a, and the reason for such changes;

6. a summary of any changes or amendments to Parkland's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;

7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have

completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);

8. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.2 and the reasons for such changes (e.g., change in contractor policy);

9. the following information regarding each type of training required by Section III.C:

- a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
- b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions; and
- c. with respect to active medical staff members, the number and percentage who completed the training, the type of training and the date received, and a description of Parkland's efforts to encourage medical staff members to complete the training.

A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

10. A description of all internal audits or reviews performed as a part of the Quality, Safety, and Performance Improvement Program prepared pursuant to Section III.A.4.a, any corrective action taken in response to any problems identified through these audits or reviews, and any changes to the audit and review process;

11. A description of the Quality, Safety, and Performance Improvement Department's measurement, analysis, and tracking of the performance metrics included in Parkland's Dashboard, Parkland's progress towards its quality improvement goals, and any changes to the Dashboard and the reasons for such changes;

12. a complete copy of the Compliance Program Review Report and Quality Program Review Report prepared pursuant to Section III.A.6;

13. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of each ROs' engagement letter;

14. Parkland's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

15. a summary and description of any and all current and prior engagements and agreements between Parkland and the Billing IRO (if different from what was submitted as part of the Implementation Report);

16. a certification from the Billing IRO regarding its professional independence and objectivity with respect to Parkland;

17. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;

18. a log of all Reportable Quality Events that have been submitted to the QRO, pursuant Appendix D, Section B, during the reporting period. The log must indicate:

- a. whether Parkland completed all mandatory external reporting obligations to any Federal, State, and local authorities as required by law; and
- b. the status of any charges that were written off or refunded to the Federal health care programs as a result of Parkland's failure to provide services in accordance with professionally recognized standards of health care.

19. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to Policies and Procedures established by the payor do not need to be included in this aggregate Overpayment report;

20. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

21. any changes to the process by which Parkland fulfills the requirements of Section III.F regarding Ineligible Persons;
22. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
23. a description of all changes to the most recently provided list of Parkland's locations (including addresses) as required by Section V.A.16; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Parkland currently submits claims; and
24. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

1. The Implementation Report and each Annual Report shall include a certification by the Compliance Officer that:
 - a. to the best of his or her knowledge, except as otherwise described in the report, Parkland is in compliance with all of the requirements of this CIA;
 - b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
 - c. to the best of his or her knowledge, Parkland has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek

payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

2. The Implementation Report and each Annual Report shall include a certification by the Chief Quality and Safety Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Parkland is in compliance with all of the quality assurance and other clinical quality related requirements of this CIA; and
- b. he or she reviewed the report and has made reasonable inquiry regarding its contents and believes that the quality assurance and other clinical quality related information in the report is accurate and truthful.

D. Designation of Information

Parkland shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Parkland shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

E. Independent Consultative Expert Reports

1. Parkland shall submit to OIG any report or written recommendations produced by the Independent Consultative Expert pursuant to the Systems Improvement Agreement within five days of Parkland receiving any report or written recommendations from the Independent Consultative Expert.

2. Parkland shall submit to OIG any report Parkland provides to the Independent Consultative Expert pursuant to the Systems Improvement Agreement at the same time Parkland provides the report to the Monitor.

3. Any written documentation Parkland provides to the Independent Consultative Expert pursuant to the Systems Improvement Agreement shall be made available to the OIG upon request.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Parkland:

Mary S. Findley, MS, CPA, CHC
Sr. Vice President/Chief Compliance Officer
Parkland Health and Hospital System
5201 Harry Hines Blvd.
Dallas, TX 75235
Telephone: 214.590.2156

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Parkland may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Parkland's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Parkland's locations for the purpose of verifying and evaluating: (a) Parkland's compliance with the terms of this CIA; and (b) Parkland's compliance with the requirements of the Federal health care programs. The documentation described

above shall be made available by Parkland to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Parkland's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Parkland shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Parkland's employees may elect to be interviewed with or without a representative of Parkland present.

VIII. DOCUMENT AND RECORD RETENTION

Parkland shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Parkland prior to any release by OIG of information submitted by Parkland pursuant to its obligations under this CIA and identified upon submission by Parkland as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Parkland shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Parkland is expected to fully and timely comply with all of its CIA obligations.

A. Specific Performance of CIA Provisions. If OIG determines that Parkland is failing to comply with a provision or provisions of this CIA and decides to seek specific performance of any of these provisions, OIG shall provide Parkland with prompt written notification of such determination. (This notification shall be referred to as the "Noncompliance Notice.") Parkland shall have 35 days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply; or (2) reply in writing that Parkland disagrees with the determination of noncompliance and request a hearing before an HHS Administrative Law Judge (ALJ), pursuant to the provisions set for in Section X.F of this CIA.

B. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Parkland and OIG hereby agree that failure to comply with certain

obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Parkland fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a Chief Quality and Safety Officer;
- d. a Quality, Safety, and Performance Improvement Department;
- e. the Quality, Safety, and Performance Improvement Program;
- f. the Quality of Care Dashboard;
- g. the Board compliance obligations, including retention of an Outside Expert;
- h. a written Code of Conduct;
- i. written Policies and Procedures;
- j. the training of Covered Persons, Billing and Reimbursement Covered Persons, Clinical Quality Covered Persons, and Board Members;
- k. a Disclosure Program;
- l. Ineligible Persons screening and removal requirements;
- m. notification of Government investigations or legal proceedings; and
- n. reporting of Reportable Events and Reportable Quality Events.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Parkland fails to engage and use a Billing IRO, as required in Section III.D and Appendices A and C.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Parkland fails to engage, use, pay, or provide information and access to a QRO, as required in Section III.D and Appendices B and D.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Parkland fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

5. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Parkland fails to submit any External Review Report in accordance with the requirements of Section III.D, Appendices C and D.

6. A Stipulated Penalty of \$1,500 for each day Parkland fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Parkland fails to grant access.)

7. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Parkland as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Parkland fails to submit its response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports, in accordance with the requirements of Section V.B.14.

9. A Stipulated Penalty of \$1,000 for each day Parkland fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Parkland stating the specific grounds for its determination that Parkland has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Parkland shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Parkland receives this notice from OIG of the failure to comply.) A Stipulated Penalty as

described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 8 of this Section.

C. Timely Written Requests for Extensions. Parkland may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Parkland fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Parkland receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

D. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Parkland has failed to comply with any of the obligations described in Section X.B and after determining that Stipulated Penalties are appropriate, OIG shall notify Parkland of: (a) Parkland's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Parkland shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.F. In the event Parkland elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Parkland cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.E.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.E.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Parkland has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.E, below.

E. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a repeated or flagrant violation of the obligations under this CIA, including but not limited to the obligations addressed in Section X.B;
- b. a violation of any obligation under this CIA that has a material impact on the quality of patient care;
- c. a failure by Parkland to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.D;
- e. a failure to respond to a Noncompliance notice concerning specific performance in accordance with Section X.A;
- f. a failure to engage and use a Billing IRO in accordance with Section III.D and Appendices A and C; or
- g. a failure to engage, use, pay, or provide information and access to the QRO in accordance with Section III.D and Appendices B and D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Parkland constitutes an independent basis for Parkland's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Parkland has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Parkland of: (a) Parkland's material breach;

and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Parkland shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Parkland is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) Parkland has begun to take action to cure the material breach; (ii) Parkland is pursuing such action with due diligence; and (iii) Parkland has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Parkland fails to satisfy the requirements of Section X.E.3, OIG may exclude Parkland from participation in the Federal health care programs. OIG shall notify Parkland in writing of its determination to exclude Parkland. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.F, below, the exclusion shall go into effect 30 days after the date of Parkland's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Parkland may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

F. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Parkland of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Parkland shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. §

1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Parkland was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Parkland shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Parkland to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Parkland requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Parkland was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Parkland had begun to take action to cure the material breach within that period; (ii) Parkland has pursued and is pursuing such action with due diligence; and (iii) Parkland provided to OIG within that period a reasonable timetable for curing the material breach and Parkland has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Parkland, only after a DAB decision in favor of OIG. Parkland's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Parkland upon the issuance of an ALJ's decision in

favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Parkland may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Parkland shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Parkland, Parkland shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Parkland and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Parkland.
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA.
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.
- D. OIG may agree to a suspension of Parkland's obligations under this CIA based on a certification by Parkland that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If Parkland is relieved of its CIA obligations, Parkland will be required to notify OIG in writing at least 30 days in advance if Parkland plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.
- E. The undersigned Parkland signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents

that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

- F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF PARKLAND

/Robert L. Smith/

5/24/13

ROBERT L. SMITH
Interim Chief Executive Officer
Parkland Health and Hospital System

DATE

/Mary S. Findley/

5/24/13

MARY S. FINDLEY, MS, CPA, CHC
Sr. Vice President/Chief Compliance and Ethics Officer
Parkland Health and Hospital System

DATE

/Paul S. Leslie/

5/24/13

PAUL S. LESLIE
General Counsel
Parkland Health and Hospital System

DATE

/Roger S. Goldman/

5/28/13

ROGER S. GOLDMAN
Latham and Watkins, LLP
Counsel for Parkland

DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Robert K. DeConti/

5/30/13

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Andrea L. Treese Berlin/

5/28/13

ANDREA L. TREESE BERLIN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Katherine Matos/

5/28/13

KATHERINE MATOS
Associate Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX A

BILLING INDEPENDENT REVIEW ORGANIZATION

A. Billing IRO Engagement

1. Parkland shall engage a Billing IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The Billing IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.14 of the CIA or any additional information submitted by Parkland in response to a request by OIG, whichever is later, OIG will notify Parkland if the IRO is unacceptable. Absent notification from OIG that the Billing IRO is unacceptable, Parkland may continue to engage the Billing IRO.

2. If Parkland engages a new Billing IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new Billing IRO is engaged, Parkland shall submit the information identified in Section V.A.14 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Parkland at the request of OIG, whichever is later, OIG will notify Parkland if the IRO is unacceptable. Absent notification from OIG that the Billing IRO is unacceptable, Parkland may continue to engage the IRO.

B. Billing IRO Qualifications

The Billing IRO shall:

1. assign individuals to conduct the Claims Review and Unallowable Cost Review who have expertise in the billing, coding, reporting, and other requirements of hospital claims and in the general requirements of the Federal health care program(s) from which Parkland seeks reimbursement;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements); and

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. Billing IRO Responsibilities

The Billing IRO shall:

1. perform each Claims Review and Unallowable Cost review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare, Medicaid, and other Federal health care programs rules and reimbursement guidelines in making assessments in the Claims Review;
3. if in doubt of the application of a particular Medicare, Medicaid, and other Federal health care programs policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);
4. respond to all OIG inquires in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix C to the CIA.

D. Billing IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. Billing IRO Removal/Termination

1. *Parkland and Billing IRO.* If Parkland terminates its Billing IRO engaged under Paragraph A.1 of this Appendix or if the Billing IRO withdraws from the engagement during the term of the CIA, Parkland must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Parkland must engage a new Billing IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the Billing IRO.

2. *OIG Removal of Billing IRO.* In the event OIG has reason to believe the Billing IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Parkland to engage a new Billing IRO in accordance with Paragraph A.1 of this Appendix. Parkland must engage a new Billing IRO within 60 days of termination of the Billing IRO.

Prior to requiring Parkland to engage a new Billing IRO, OIG shall notify Parkland of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Parkland may present additional information regarding the Billing IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the Billing IRO with Parkland prior to requiring Parkland to terminate the Billing IRO. However, the final determination as to whether or not to require Parkland to engage a new Billing IRO shall be made at the sole discretion of OIG.

APPENDIX B

QUALITY REVIEW ORGANIZATION

A. Quality Review Organization Engagement

1. Within 60 days after the Effective Date, Parkland shall retain an appropriately qualified monitoring team, the QRO, selected by OIG after consultation with Parkland. The QRO may retain additional personnel, including but not limited to independent consultants, if needed to help meet the QRO's obligations under this CIA. The QRO may confer and correspond with Parkland or OIG individually or together. The QRO and Parkland shall not negotiate or enter into a financial relationship, other than the monitoring engagement required by this section, until after the date of OIG's CIA closure letter to Parkland or six months after the expiration of this CIA, whichever is later.

2. The QRO is not an agent of OIG. However, the QRO may be removed by OIG at its sole discretion. If the QRO resigns or is removed for any other reasons prior to the termination of the CIA, Parkland shall retain, within 60 days of the resignation or removal, another QRO selected by OIG after consultation with Parkland, with the same functions and authorities.

B. QRO Responsibilities

The QRO shall:

1. perform a Clinical Quality Systems Review, in accordance with the specific requirements of Appendix D to the CIA;
2. apply professionally recognized standards of care in making assessments in the Clinical Quality Systems Review;
3. respond to all OIG inquires in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by Appendix D to the CIA.

C. QRO Qualifications. The QRO's employees shall have expertise in evaluating clinical quality management in the acute care setting.

D. Financial Obligations of Parkland and the QRO

1. Parkland shall be responsible for all reasonable costs incurred by the QRO in connection with this engagement, including but not limited to labor costs (direct and indirect); consultant and subcontract costs; materials cost (direct and indirect); and other direct costs (travel, other miscellaneous).

2. Parkland shall pay the QRO's bills within 30 days of receipt, unless otherwise negotiated with the QRO. Failure to pay the QRO within 30 calendar days of submission of the QRO's invoice for services previously rendered shall constitute a basis to impose stipulated penalties or exclude Parkland, as provided under Section X.3 of the CIA. While Parkland must pay all of the QRO's bills within 30 days, Parkland may bring any disputed QRO's Costs or bills to OIG's attention.

3. The QRO shall charge a reasonable amount for its fees and expenses. The QRO shall submit a written report for each Reporting Period representing an accounting of its costs throughout the year to Parkland and to OIG by the submission deadline of Parkland's Annual Report.

E. Additional Parkland Obligations.

Within 60 days after a QRO is retained by Parkland or 120 days after the Effective Date of the CIA, whichever is later, Parkland shall provide the QRO with all reports issued by the ICE in connection with the SIA.

APPENDIX C

CLAIMS REVIEW

A. Claims Review. The Billing IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The Billing IRO shall perform all components of each Claims Review.

1. *Definitions*. For the purposes of the Claims Review, the following definitions shall be used:

- a. Overpayment: The amount of money Parkland has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Paid Claim: A claim submitted by Parkland during the relevant review period and for which Parkland has received reimbursement from Medicare and/or Medicaid.
- c. Population:
 - i. Medicare Population: For the purposes of Medicare Paid Claims, the Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.
 - ii. Medicaid Population: For the purposes of Medicaid Paid Claims, the Population for the First Reporting Period shall be defined as all Paid Claims for the six-month period from the Effective Date to the mid-point of the First Reporting Period. For the Second, Third, and Fourth Reporting Periods, the Population will be defined as the 12-month period covered from mid-point to mid-point of each reporting period. For the Fifth Reporting Period, the Population shall be defined as the 18-month period from the mid-point of the Fourth Reporting Period to the end of the Fifth Reporting Period.

With 180 days' notice and after consultation with Parkland, the OIG, at its sole discretion, can narrow the Population.

- d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

2. *Discovery Sample*. The Billing IRO shall randomly select and review a sample of 200 Paid Claims (Discovery Sample) each Reporting Period. The Paid Claims reviewed shall be comprised of four strata (Strata) as follows: 50 Medicare inpatient Paid Claims, 50 Medicare outpatient Paid Claims, 50 Medicaid inpatient Paid Claims, and 50 Medicaid outpatient Paid Claims. Each Strata shall be reviewed separately. The Paid Claims shall be reviewed based on the supporting documentation available at Parkland's office or under Parkland's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for any Strata of the Discovery Sample is less than 5%, no additional sampling for that Strata is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Parkland should, as appropriate, further analyze any errors identified in the Discovery Sample. Parkland recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample*. If the Discovery Sample indicates that the Error Rate for any Strata is 5% or greater, the Billing IRO shall select an additional sample of Paid Claims (Full Sample) in that Strata using commonly accepted sampling methods. The Full Sample shall be designed to: (1) estimate the actual Overpayment in the population

with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at Parkland or under Parkland's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the Billing IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the Billing IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related work papers) received from Parkland to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

4. *Systems Review.* If Parkland's Discovery Sample identifies an Error Rate of 5% or greater in any Strata, Parkland's Billing IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

- a. a review of Parkland's billing and coding systems and processes relating to claims submitted to Federal health care programs (including but not limited to the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);
- b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the Billing IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The Billing IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements*

- a. Supplemental Materials. The Billing IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and Parkland shall furnish such documentation and materials to the Billing IRO prior to the Billing IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the Billing IRO accepts any supplemental documentation or materials from Parkland after the Billing IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the Billing IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the Billing IRO gave to the Supplemental Materials in its review. In addition, the Billing IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the Billing IRO's reasons for accepting the Supplemental Materials.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which Parkland cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Parkland for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

6. *Repayment of Identified Overpayments*. Parkland shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with

payor refund policies. Parkland shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The Billing IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology*

- a. Claims Review Population. A description of the Population subject to the Claims Review.
- b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
- c. Source of Data. A description of the specific documentation relied upon by the Billing IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
- d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by A.5.a., above.

2. *Statistical Sampling Documentation*

- a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the Billing IRO.
- b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.

- c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings*

a. Narrative Results

- i. A description of Parkland's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
- ii. A narrative explanation of the Billing IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results

- i. Total number and percentage of instances in which the Billing IRO determined that the Paid Claims submitted by Parkland (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.
- ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Parkland.
- iii. Total dollar amount of all Overpayments in the sample.
- iv. Total dollar amount of Paid Claims included in the sample and the net Overpayment associated with the sample.
- v. Error Rate in the sample.

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the Billing IRO), correct allowed amount (as determined by the Billing IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

c. Recommendations. The Billing IRO's report shall include any recommendations for improvements to Parkland's billing and coding system based on the findings of the Claims Review

4. *Systems Review Findings.* The Billing IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the Billing IRO's observations, findings, and recommendations regarding:

- a. the strengths and weaknesses in Parkland's billing systems and processes;
- b. the strengths and weaknesses in Parkland's coding systems and processes; and
- c. possible improvements to Parkland's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.

APPENDIX D

CLINICAL QUALITY SYSTEMS REVIEW

The QRO shall perform a Clinical Quality Systems Review annually to cover each of the five Reporting Periods. The QRO shall perform all components of each Clinical Quality Systems Review.

A. Clinical Quality Systems Review

The QRO shall perform a Clinical Quality Systems Review to assess the effectiveness, reliability, and thoroughness of Parkland's quality management infrastructure and systems throughout Parkland. The QRO shall assess Parkland's efforts to achieve compliance with its Clinical Quality Policies and Procedures described in Section III.B.2.b-c, the Medicare Conditions of Participation, and other standards designed to ensure that the delivery of patient care items or services at Parkland meet professionally recognized standards of health care and are reasonable and appropriate to the needs of Federal health care program beneficiaries. The Clinical Quality Systems Review will be undertaken at all relevant levels of the organization. The QRO shall assess, among other things, the effectiveness, reliability, and thoroughness of the following:

1. Parkland's quality management infrastructure, including but not limited to an assessment of:
 - a. Parkland's Quality of Care Dashboard required under section III.A.4.b. of this CIA;
 - b. The accuracy of Parkland's internal reports, data, and assessments required by the Clinical Quality Policies and Procedures;
 - c. Parkland's ability to analyze outcome measures and other data;
 - d. The extent to which reviews under Parkland's Quality, Safety, and Performance Improvement Program and other reviews are occurring to identify and address quality management issues at Parkland;

- e. Parkland’s compliance with the Clinical Quality Training requirements, Clinical Quality Policies and Procedures, and performance standards of Section III.B.2.b–c & III.C.3 of the CIA;
- f. The extent to which Parkland’s Clinical Quality Training program is effective, thorough, and competency-based;
- g. The extent to which Parkland’s communication systems are effective and results of decisions are transmitted to the proper individuals in a timely fashion.

2. Parkland’s response to quality of care issues, which shall include an assessment of:

- a. Parkland’s ability to identify the problem;
- b. Parkland’s ability to determine the scope of the problem (e.g., systemic or isolated);
- c. Parkland’s ability to conduct a root cause analysis;
- d. Parkland’s ability to create a corrective action plan to respond to the problem;
- e. Parkland’s ability to execute the corrective action plan;
- f. Parkland’s ability to operate in a timely and effective manner; and
- g. Parkland’s ability to monitor and evaluate whether the assessment, corrective action plan, and execution of that plan were effective, reliable, thorough, and maintained.

3. Parkland’s proactive steps to ensure that each patient receives care in accordance with:

- a. professionally recognized standards of health care;
- b. the Conditions for Participation for Hospitals, 42 CFR Part 485;

- c. State and local statutes, regulations, and other directives or guidelines;
- d. the Policies and Procedures adopted by Parkland, including those implemented under Section III.B.2.b-c of this CIA; and
- e. professionally recognized standards of clinical staffing.

4. Parkland's identification and response to Reportable Quality Events, as required by Section B of this Appendix D.

B. Reportable Quality Events

1. *Definition of Reportable Quality Event.* For purposes of this CIA, a "Reportable Quality Event" means anything that involves:

- a. Deaths or injuries related to use of restraints;
- b. Deaths or injuries related to use of psychotropic medications;
- c. Suicides;
- d. Deaths or injuries related to abuse or neglect (as defined in the applicable Federal guidelines);
- e. Never events;
- f. An incident in which items or services furnished to a patient are substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care; and
- g. Any other incident that involves or causes actual harm to a patient when such incident is required to be reported to any local, State, or Federal government agency.

2. If Parkland determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Quality Event, Parkland shall notify the QRO, in writing, within 60 days after making the determination that the Reportable Quality Event exists.

3. For Reportable Quality Events, the report to the QRO shall include:
 - a. a complete description of the Reportable Quality Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
 - b. a description of Parkland's actions taken to correct the Reportable Quality Event;
 - c. any further steps Parkland plans to take to address the Reportable Quality Event and prevent it from recurring; and
 - d. if the Reportable Quality Event has resulted in an Overpayment, a description of the steps taken by Parkland to identify and quantify the Overpayment.

4. Parkland shall provide all reports to the QRO of Reportable Quality Events to its Compliance Committee, Quality, Safety, and Performance Improvement Department, Audit and Compliance Committee, and Quality of Care and Patient Safety Committee.

C. Access. The QRO shall have:

1. immediate access to Parkland, at any time and without prior notice, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate;
2. immediate access to:
 - a. internal or external surveys, assessments, or reports;
 - b. Reportable Quality Event disclosures;
 - c. the Quality of Care Dashboard and related documents;
 - d. documents related to any clinical quality training;
 - e. Clinical Quality Policies and Procedures;
 - f. staffing data in the format requested by the QRO contract;

- g. reports of abuse, neglect, or an incident that resulted in patient harm;
- h. reports of any incident involving a patient that prompts a full internal investigation;
- i. patient records;
- j. documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and
- k. any other data in the format the QRO determines relevant to fulfilling the duties required under this CIA;

3. immediate access to patients and Covered Persons for interviews outside the presence of Parkland supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The QRO shall give full consideration to an individual's clinical condition before interviewing a patient.

D. Clinical Quality Systems Review Report

The QRO shall prepare a report based upon each Clinical Quality Systems Review performed (Clinical Quality Systems Review Report).

1. the Clinical Quality Systems Report shall set forth, at a minimum:
 - a. a summary of the QRO's activities in conducting the assessment;
 - b. the QRO's findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section A.1 of this Appendix;
 - c. the QRO's recommendations to Parkland as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.A.1 of this Appendix;

- d. an assessment of Parkland's response to the QRO's prior recommendations; and
- e. an assessment of Parkland's compliance with the Reportable Quality Events provisions as required by Section B of this Appendix D, including, at a minimum, the sufficiency of Parkland's actions to correct each Reportable Quality Event, and Parkland's steps to address and prevent the recurrence of each Reportable Quality Event.

E. Additional QRO Obligations. The QRO shall:

1. abide by all State and Federal laws and regulations concerning the privacy, dignity, and employee rights of all Covered Persons and patients;
2. abide by the legal requirements of Parkland to maintain the confidentiality of each patient's personal and clinical records. Nothing in this subsection, however, shall limit or affect the QRO's obligation to provide information, including information from patient clinical records, to OIG, and, when legally or professionally required, to other agencies;
3. where independently required to do so by applicable law or professional licensing standards, report any finding to an appropriate regulatory or law enforcement authority, and simultaneously submit copies of such reports to OIG and to Parkland;
4. not be bound by any other private or governmental agency's findings or conclusions, including but not limited to the Joint Commission, CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the QRO's findings or conclusions. The QRO's reports shall not be the sole basis for determining deficiencies by the state survey agencies. The parties agree that CMS and its contractors shall not introduce any material generated by the QRO, or any opinions, testimony, or conclusions from the QRO as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against Parkland, and Parkland shall similarly be restricted from using material generated by the QRO, or any opinions, testimony, or conclusions from the QRO as evidence in any of these proceedings. Nothing in the previous sentence, however, shall preclude OIG or Parkland from using any material generated by the QRO, or any opinions, testimony, or conclusions from the QRO in any action under the CIA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;

5. abide by the provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 to the extent required by law including, without limitation, entering into a business associate agreement with Parkland; and

6. if the QRO has concerns about systemic problems that could affect Parkland's ability to render quality care to its patients, then the QRO shall:

- a. report such concerns in writing to OIG; and
- b. simultaneously provide notice and a copy of the report to Parkland's Compliance Committee, Quality, Safety, and Performance Improvement Department, Audit and Compliance Committee, and Quality of Care and Patient Safety Committee referred to in Section III.A of this CIA.